UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, and WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA,

ex rel. JOHN DOE,

Plaintiffs,

v.

INTERCEPT PHARMACEUTICALS, INC., a Delaware corporation; THE ASSISTANCE FUND, INC., a Delaware corporation; TMS HEALTH, LLC, a Delaware corporation; TMS HEALTH PATIENT ACCESS SOLUTIONS, a business entity of unknown form; CONDUENT PATIENT ACCESS SOLUTIONS, LLC, a New Jersey corporation; and CONDUENT INCORPORATED, a New York corporation,

Defendants.

CIVIL ACTION NO.:

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

COMPLAINT

PLAINTIFF-RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

Pursuant to the Federal False Claims Act, as well as various state analogs, Plaintiff-Relator John Doe ("Relator") hereby brings the within action against Defendants, and Relator states as follows:

INTRODUCTION

1. Relator John Doe brings this action on behalf of the United States of America, 28 States ("the Plaintiff States"),[1] and the District of Columbia ("the District") to recover monies wrongfully paid by those entities as a result of false claims caused by Defendants. Relator brings this action pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, and pursuant to the *qui tam* provisions of the analog false claims acts of the Plaintiff States and the District (*see* Counts III-XXXI, *infra*). Pursuant to 31 U.S.C. § 3730(b)(2) and comparable state-law provisions, this action is brought *in camera* and under seal.

2. Intercept is a pharmaceutical company that currently manufactures and distributes a single drug product: Ocaliva (obeticholic acid). Ocaliva is approved by the United States Food & Drug Administration ("FDA") for the treatment of primary biliary cholangitis ("PBC") in combination with ursodeoxycholic acid ("UDCA") in adults with an inadequate response to UDCA, or as monotherapy in patients unable to

[1] The 28 "Plaintiff States" on whose behalf Relator brings this action are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington.

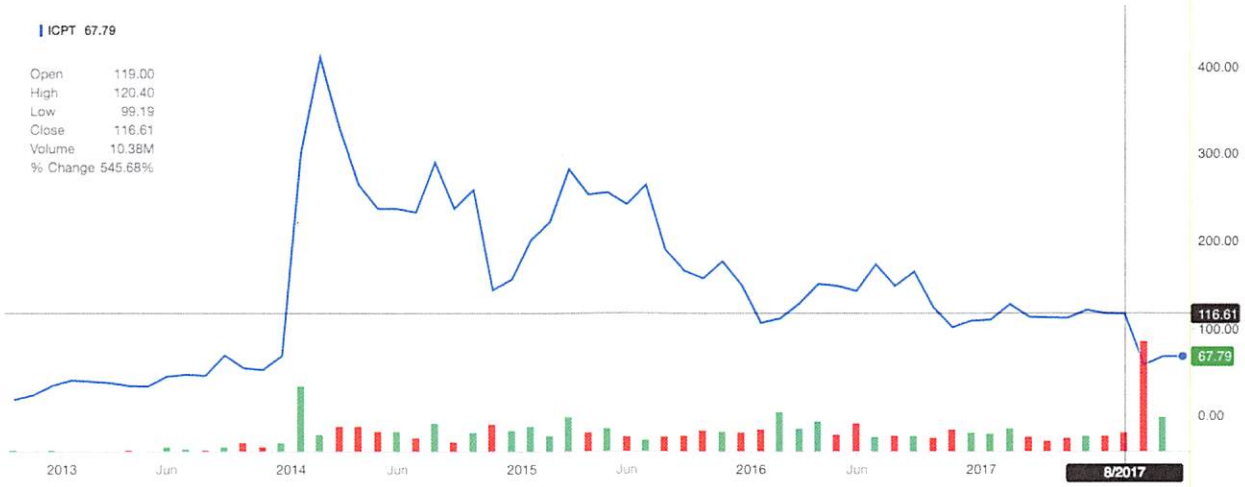
tolerate UDCA. PBC is a rare and slowly-progressive cholestatic liver disease that affects women ten times more frequently than men.

3. The FDA estimates that there are 20,000 people in the United States with PBC. Due to its rarity, PBC qualifies as an "orphan disease" under FDA regulations. In May 2016, the FDA approved Ocaliva as an "orphan drug." This type of approval was critical, because it allowed Intercept, among other things, to bypass the usual clinical trial testing requirements. The rarity and severity of PBC also has allowed Intercept to set its own exorbitant price for the drug: a year's worth of therapy currently costs $69,350.

4. More importantly, orphan drug approval can be a gateway to a vast off-label market. In the case of Ocaliva, the significant profit potential lies in the treatment of an off-label condition called nonalcoholic steatohepatitis ("NASH"). Although there are approximately 20,000 patients in the United States with PBC, that patient population pales in size compared to the off-label market for NASH patients, which is estimated to be somewhere between 6 million and 16 million Americans – thus potentially making Ocaliva a blockbuster drug were it used to treat NASH patients. After the FDA approved Ocaliva to treat PBC, Intercept specifically targeted NASH patients for off-label marketing of Ocaliva. Indeed, such off-label marketing has caused a tremendous (and unlawful) growth in Ocaliva prescriptions, many of which are paid for by government health care programs.

5. The reaction from investors to Intercept's forecasts has been dramatic. The price of Intercept's stock appreciated forty-fold since its public debut of $20 per

share to a peak of $462 per share. And, despite a recent decline in the company's stock price, Intercept's market capitalization is still approximately $1.7 billion.



6. Defendants knowingly and deliberately have engaged, and continue to engage, in conduct they know will lead to violations of federal Medicare and Medicaid statutes and regulations designed to restrict government reimbursement for Ocaliva. Defendants intentionally have embarked on a course of unlawful conduct that they know has led, and will continue to lead, to the submission by physicians and pharmacists of hundreds and perhaps ultimately thousands of Medicare and Medicaid claims for Ocaliva for patients that do not have PBC. Accordingly, Defendants are liable for knowingly causing these false claims to be presented to the United States for payment in violation of 31 U.S.C. § 3729. Defendants are similarly liable for causing false claims to be presented to the Plaintiff States and the District under their respective false claims acts.

PARTIES

7. Relator, John Doe, is a veteran in the field of pharmaceutical reimbursement and the former Intercept Director of Strategic Accounts. Relator held this position from August 2015 through June 2017.

8. Defendant Intercept Pharmaceuticals, Inc. ("Intercept") is a Delaware corporation with its principal place of business in New York, New York. Intercept conducts business in each and every state in the United States.

9. Defendant The Assistance Fund, Inc. (the "Fund") is a Delaware corporation with its principal place of business in Orlando, Florida.

10. Defendant Conduent Incorporated ("Conduent") is a publicly-traded New York corporation (NYSE ticker symbol "CNDT") with its principal place of business located at 100 Campus Drive, Florham Park, New Jersey 07932. Conduent is the parent company of Defendant TMS Health, LLC.

11. Defendant TMS Health, LLC ("TMS Health") is a Delaware corporation with its principal place of business in Boca Raton, Florida. Upon information and belief, TMS Health is a subsidiary of, and controlled by, Conduent; upon further information and belief, TMS Health is an alter ego of Conduent and the separate corporate identity of TMS Health should be disregarded such that Conduent is jointly and severally responsible and liable for the actions and/or omissions of TMS Health.

12. Defendant TMS Health Patient Access Solutions ("TMS-HPAS") is a business entity of unknown form. Upon information and belief, TMS-HPAS is part of TMS Health and/or TMS-HPAS is a DBA of TMS Health and Conduent; upon further

information and belief, TMS-HPAS is an alter ego of TMS Health and Conduent and the separate business identity of TMS-HPAS should be disregarded such that TMS Health and Conduent are jointly and severally responsible and liable for the actions and/or omissions of TMS-HPAS.

13. Defendant Conduent Patient Access Solutions, LLC ("CPAS") is a New Jersey corporation with its principal place of business in Somerset, New Jersey. Upon information and belief, CPAS is a subsidiary of, and controlled by, Conduent; upon further information and belief, CPAS is an alter ego of Conduent and the separate corporate identity of CPAS should be disregarded such that Conduent is jointly and severally responsible and liable for the actions and/or omissions of CPAS.

14. Unless otherwise stated herein, all references hereafter in this Complaint to TMS Health are intended to include both TMS-HPAS and CPAS.

15. Unless otherwise stated herein, each Defendant was the agent, joint venturer, partner, and/or affiliate of each of the other Defendants; and in doing the things hereinafter alleged, each Defendant was acting within the course and scope of said agency, joint venture, partnership, and/or affiliation with the advance knowledge, acquiescence, or subsequent ratification of each of the other Defendants – such that each Defendant is jointly and severally responsible and liable for the actions and/or omissions of each of the other Defendants.

JURISDICTION AND VENUE

16. Pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in

particular the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). In addition, the FCA specifically confers jurisdiction upon this Court pursuant to 31 U.S.C. § 3732(b).

17. Pursuant to 28 U.S.C. § 1367, this Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the Plaintiff States and the District on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

18. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process, and because Defendants have sufficient minimum contacts with the United States of America.

19. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because one or more of the Defendants transacts business in this judicial district.

20. Relator is unaware of any public disclosure of the information or allegations that are the basis of this Complaint. In the event that there has been a "public disclosure" as defined by law of the actionable information or allegations that are contained in this Complaint, Relator is an "original source" as defined by law with respect to any such disclosed information or allegations. The fact that many thousands of claims presented to government health care programs (including Medicare and Medicaid) were inaccurate in the manner described in this Complaint is a material fact, which if known to the United States, the Plaintiff States, and/or the District would have

caused them to deny paying those claims. Prior to filing this action, Relator voluntarily provided information to the United States, the Plaintiff States, and the District regarding the false/fraudulent claims that are the subject of this Complaint. Relator did so on or about October 13, 2017.

FEDERAL AND STATE FALSE CLAIMS ACTS

21. The Federal False Claims Act (the "FCA"), 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains; plus a civil monetary penalty of not less than $10,781 nor more than $21,563 per claim for claims made after November 2, 2015.

22. The FCA, 31 U.S.C. § 3729(a)(1)(B), makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains; plus a civil monetary penalty of not less than $10,781 nor more than $21,563 per claim for claims made after November 2, 2015.

23. The FCA, 31 U.S.C. § 3729(a)(1)(C)), makes any person, who conspires to commit a violation of the FCA, liable for three times the amount of the damages the Government sustains; plus a civil monetary penalty of not less than $10,781 nor more than $21,563 per claim for claims made after November 2, 2015.

24. The FCA defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

25. The FCA, 31 U.S.C. § 3729(b)(1), provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

26. The FCA, 31 U.S.C. § 3729(b)(4), provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

GOVERNMENT HEALTH INSURANCE PROGRAMS

27. The Health Insurance for the Aged and Disabled Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395, *et seq.* (popularly known as "Medicare"), is a health insurance program administered by the United States that is funded by taxpayer revenue. Medicare is overseen by the United States Department of Health and Human Services ("HHS") through its Centers for Medicare and Medicaid Services ("CMS").

28. Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services, and durable medical equipment

for persons over sixty-five (65) years of age; and for certain others that qualify under the terms and conditions of the program, including many individuals who are permanently disabled under the Social Security Act.

29. Reimbursement for Medicare claims is made by the United States through CMS, which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the private insurance carriers act on behalf of CMS.

30. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396–1396v (hereafter "Medicaid"), is a health insurance program administered by the United States and the various individual states that is funded by both federal and state taxpayer revenue. The United States uses CMS to oversee Medicaid.

31. Medicaid was designed to assist participating states in providing hospital services, medical services, durable medical equipment, and prescription drugs to, among others, financially-needy individuals that qualify for Medicaid. The states directly pay providers, with the states obtaining the federal share of the payment from accounts that draw on the United States Treasury. *See* 42 C.F.R. §§ 430.0–430.30 (1994).

32. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS" – now known as "TRICARE"), 10 U.S.C. §§ 1071–1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the uniformed services and to spouses and children of active duty, retired, and deceased members. The program is administered by the Department of Defense and funded by the federal government.

33. The federal government, through its Departments of Defense and Veterans Affairs, maintains and operates medical facilities including hospitals, and receives and uses federal funds to purchase medical devices for patients treated at such facilities and otherwise.

34. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, medical devices for its beneficiaries. (Together, all of the programs described above in Paragraphs 27-34, and any other government funded health care programs, shall be referred to as "Government Health Care Programs.")

35. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid, and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. § 410.50. Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See id.*

36. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute (discussed below) and with other federal laws governing the provision of health care services in the United States. That agreement

represents an ongoing obligation, and the provider must notify the government of any change in information or certifications provided.

37. In other words, if a provider were to tell CMS or its agent that it had provided goods or services that were in violation of the Anti-Kickback Statute, that were not medically unnecessary, that were performed solely for the profit of the provider, and/or that violated another relevant law, then CMS would not pay the claim.

FEDERAL AND STATE ANTI-KICKBACK LAWS

38. The Medicare and Medicaid Patient Protection Act, also known as "the Anti-Kickback Statute" ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupt medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of Government Health Care Programs, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093.

39. In 1977, Congress amended the AKS to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a

misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the AKS was to combat fraud and abuse in medical settings that "cheat[ ] taxpayers who must ultimately bear the financial burden of misuse of funds . . . [that] divert[ ] from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and that] erode[ ] the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." H.R. Rep. No. 95–393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.[2]

40. In 1987, Congress again strengthened the AKS to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

41. The AKS prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good, service, or item for which payment may be made in whole or in part by a Government Health Care Program (*e.g.*, Medicare), which

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[2] Congress sought to "give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public and the public purse." 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997) (Sen. Talmadge statement).

also includes any state health program funded in part by the federal government (*e.g.*, Medicaid). 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

42. The AKS provides, in pertinent part:

> (b) ***Illegal remunerations***
>
> * * *
>
> (2) Whoever knowingly and willfully ***offers or pays any remuneration*** (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, ***in cash or in kind***
> to any person ***to induce such person –***
>
> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
>
> (B) ***To purchase***, lease, order or arrange for or recommend purchasing, leasing or ordering ***any good***, facility, ***service, or item*** for which payment may be made in whole or in part under a Federal health care program,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b) (emphasis added).

43. The AKS not only prohibits outright bribes and rebate schemes, but it also prohibits any ***payment, gift, or other remuneration*** by a company to a physician or other person (*e.g.*, a patient or customer) which has as one of its purposes the inducement of the physician ***or patient*** to use the company's products.

44. In addition to criminal penalties, a violation of the AKS can also subject the perpetrator to exclusion from participation in Government Health Care Programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

45. Compliance with the AKS is a precondition to participation as a health care provider under all Government Health Care Programs, including Medicare and state Medicaid programs. Moreover, compliance with the AKS is a ***condition of payment*** for any claims for which Medicare or Medicaid reimbursement is sought. Either pursuant to provider agreements, claims forms, hospital costs reports, or other appropriate manner, physicians, hospitals, and other providers who participate in Government Health Care Programs must certify that they have complied with all applicable federal rules and regulations, including the AKS. For example, every provider who enters into a contract with Medicare specifically acknowledges in its provider contract that the provider understands "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider]'s compliance with all applicable conditions of participation in Medicare." Upon information and belief, each of the Plaintiff States' and the District's provider agreements in their respective Medicaid programs contains comparable provisions requiring providers to agree to

comply with the AKS and acknowledging that their receipt of payment is conditioned upon compliance with such provisions.

46. Medicare and Medicaid claims for reimbursement of any goods or services that were the subject of a kickback constitute false claims (*see* False Claims Act discussion, *supra*). This is because compliance with the AKS is a precondition to participation as a health care provider under all Government Health Care Programs, including Medicare and state Medicaid programs. Moreover, compliance with the AKS is a condition of payment for any goods or services reimbursed by Medicare or Medicaid.

47. Furthermore, the AKS was amended, effective March 23, 2010, to expressly provide that: "In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Consequently, any kickbacks paid by Defendants on or after March 23, 2010, that caused reimbursement claims to be presented to Government Health Care Programs for payment would result in actionable false claims regardless of the provisions of any provider agreement.

48. When a kickback has been paid, the measure of damages is the full amount of the claim caused by the kickback – such as the amounts billed to Medicare or Medicaid for an Ocaliva prescription. All such kickback-tainted payments are owed back to the government.

49. At all relevant times mentioned herein, Defendants were sophisticated and fully aware of the federal and state anti-kickback laws that prohibit unlawful remuneration in connection with Government Health Care Programs, and also aware of federal and state false claims act laws. For example, Defendant Intercept has two sections in its 2016 Form 10-K Annual Report entitled "U.S. Fraud and Abuse Laws" and "Other Laws" wherein the company explains:

> Any present or future arrangements with third-party payors, healthcare providers and professionals and customers may expose us to broadly applicable federal and abuse and healthcare laws and regulations that may restrict certain marketing and contracting practices. These laws include, and are not limited to, anti-kickback and false claims statutes.
>
> . . . .
>
> A number of states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act that apply to items and services reimbursed under Medicaid and other state programs.

Intercept's 2016 Form 10-K at 30-31 (copy available online at Intercept's website, *interceptpharma.com*, under the "Investors & Media" tab).

50. As discussed more fully below, from 2016 through the present, the United States (through Medicare, Medicaid, and other Government Health Care Programs), and the Plaintiff States and the District (through Medicaid), have paid ***millions of dollars in false and/or fraudulent claims*** for Ocaliva prescriptions purchased from Intercept that were tainted by Defendants' knowingly having paid millions of dollars in kickbacks to the Ocaliva patients/customers – *i.e.*, via the unlawful subsidization of co-payment amounts for Ocaliva prescriptions.

FACTUAL ALLEGATIONS

I. OCALIVA

51. Ocaliva is FDA-approved for the treatment of primary biliary cholangitis ("PBC")[3] in combination with ursodeoxycholic acid ("UDCA") in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. PBC is a rare and slowly-progressive cholestatic liver disease that affects women ten times more frequently than men. PBC causes the bile ducts in the liver to become inflamed, damaged and destroyed. This causes bile, a fluid that helps in digestion, to build up in the liver. This build-up damages the liver over time, eventually causing the liver to lose function. However, Ocaliva has been shown to improve a certain blood test that measures liver problems.

52. Due to its rarity, PBC qualifies as an "orphan disease" under FDA regulations. In May 2016, the FDA approved Ocaliva as an "orphan drug." This type of approval was critical, because it allowed Intercept to bypass the usual clinical trial testing requirements. The rarity and severity of PBC also has allowed Intercept to set its own exorbitant price for the drug: a year's worth of therapy at the maximum approved dosage currently costs $69,350. According to internal Intercept documents, at least 300

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[3] PBC was originally known as primary biliary cirrhosis. Thanks to earlier diagnosis, however, it was renamed as primary biliary cholangitis because the majority of patients do not have cirrhosis at the time of diagnosis.

Medicare Part D patients are actively taking Ocaliva, accounting for 22% of patient enrollment at a cost of about $21,000,000 per annum.

53. Orphan drugs receive a variety of benefits not available for other drugs. First and foremost, orphan drugs can more easily and cheaply gain FDA approval, avoiding the need to obtain as rigorous evidence of safety and efficacy as non-orphan drugs. Second, there are various financial incentives, including federal research grants, tax credits, extended marketing exclusivity, and waiver of the FDA's user fees.

54. More importantly, orphan drug approval can be a gateway to a vast off-label market. In the case of Ocaliva, the significant profit potential lies in the treatment of an off-label condition called nonalcoholic steatohepatitis ("NASH"). Although there are approximately 20,000 patients in the United States with PBC, that patient population pales in size compared to the off-label market for NASH patients, which is estimated to be somewhere between 6 million and 16 million Americans – thus potentially making Ocaliva a blockbuster drug were it used to treat NASH patients. The most notable feature of NASH is a buildup of fat in the liver, but its underlying cause is still not well understood. Although many patients do not feel sick, NASH can be a serious problem leading to cirrhosis and ultimately liver failure. There are currently no specific treatments for NASH.[4]

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[4] It should be noted that NASH is but one form of nonalcoholic fatty liver disease ("NAFLD"), which can lead to cirrhosis, liver failure, and cancer. It is defined by an accumulation of triglycerides in the cells of the liver with inflammation and ballooning of the liver cells with or without fibrosis. NAFLD is estimated to be present in up to 30% of the U.S. population (or 80 million adults).

55. The United States Government (through Medicare, Medicaid, and other Government Health Care Programs), the Plaintiff States (through Medicaid), and the District (through Medicaid) pay for a large percentage of all drug prescriptions in the United States.

56. Since 2006, the Medicare program has purchased prescription drugs for those persons eligible for Medicare Part D coverage. Medicare not only covers individuals over age 65, but it also provides medical coverage for many individuals who are permanently disabled under the Social Security Act.

57. Medicaid is a joint program of the United States Government and state governments to provide medical services, including prescription drugs, to persons who could not otherwise afford them. More prescription drugs are purchased through the Medicaid program than through any other insurance program in the United States. All of the Plaintiff States and the District participate in Medicaid and use Plaintiff States funds or District funds blended with federal funds for the purchase of prescription drugs.

58. Government Health Care Programs (including Medicare and Medicaid) reimburse at least 22% of the prescriptions for Ocaliva and likely much more.

59. The programs identified above spend billions of dollars each year on prescription drugs. Not surprisingly, in order to prevent waste, fraud, and abuse, and to protect the health of patients, the federal and state programs restrict the types and uses of drugs that may be paid for with government funds. These regulatory regimes

are designed to ensure that the federal and state programs only pay for drugs that are found to be safe and effective for their prescribed uses.

60. The Medicare and Medicaid programs are only authorized to purchase prescription drugs that are "covered outpatient drugs," as defined by 42 U.S.C. § 1396r-8(k)(2), and that are used for "medically accepted indications," as defined by 42 U.S.C. § 1395w-102(e)(4) (for Medicare) or 42 U.S.C. § 1396r-8(k)(6) (for Medicaid). In order to meet the definition of a "covered outpatient drug," either a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") must be approved by the FDA. In order to be used for a "medically accepted indication" under either program, the drug must be used as approved by the FDA, or its use must be supported by a citation in the accepted medical compendia. Conversely, if a drug's usage is not in compliance with its FDA-approved labeling, and if such usage is not favorably cited in one of the specified compendia, then it is not eligible for reimbursement under Medicare or Medicaid.

61. Ocaliva's sole "medically accepted indication" is for the treatment of PBC at dose not to exceed 10mg per day. Drugdex, which is the most comprehensive of the three statutory compendia referenced in 42 U.S.C. § l396r-8(g)(l)(B)(i) contains ***no support for any off-label indication***. Furthermore, Relator is not aware of there being any support for any off-label indication in peer-reviewed medical literature.

II. INTERCEPT

62. Intercept was incorporated in September 2002 as a Delaware corporation.

63. Intercept's executive officers are currently as follows: Mark Pruzanski, M.D. (CEO & President); Lisa Bright (President, International); Jerome Durso (COO); David Ford (Chief Human Resources Officer); Sandip Kapadia (CFO); Richard Kim (Senior V.P., U.S. Commercial); Rachel McMinn, Ph.D. (Chief Business and Strategy Officer); and David Shapiro, M.D. (Chief Medical Officer & E.V.P., Development).

64. The following individuals comprise Intercept's current Board of Directors: Paolo Fundarò (Chairman of the Board); Srinivas Akkaraju, M.D., Ph.D.; Luca Benatti, Ph.D; Daniel Bradbury; Keith Gottesdiener, M.D.; Mark Pruzanski, M.D.; Gino Santini; Glenn Sblendorio; and Daniel Welch.

65. Relator is a veteran in the field of pharmaceutical reimbursement, and he is the former Director of Strategic Accounts at Intercept. Relator held that position from August 2015 through June 2017.

66. Defendants' conduct in this case has caused Medicare and Medicaid (and/or other Government Health Care Programs identified above) to pay for prescriptions that were off-label and ineligible for reimbursement, and that would not otherwise have been presented for payment.

67. As set forth below, Intercept markets and promotes Ocaliva for the off-label treatment of NASH as well as in dosages outside of the FDA-approved labeling. Recently, it has become evident that increased dosing beyond the FDA label is dangerous and can be fatal.

68. The maximum daily dose of Ocaliva approved by the FDA is 10mg per day. The recommended starting dosage of Ocaliva is 5mg orally once daily in adults

who have not achieved an adequate response to an appropriate dosage of UDCA for at least 1 year or who are intolerant of UDCA. If adequate response in alkaline phosphatase ("ALP") has not been achieved after 3 months of Ocaliva 5mg once daily and the patient is tolerating the drug, then the FDA approval permits an increase in daily dosage to 10mg.

69. The dosage limitation is not arbitrary. It is based on the FDA's specific safety concerns. Indeed, these safety concerns have resulted not just in specific labeling restrictions on dosing, but also on the imposition of a Risk Evaluation and Mitigation Strategy ("REMS"). FDA regulations require its Division of Risk Management ("DRISK") to evaluate whether a new drug requires a REMS to ensure that the benefits of the drug outweigh its risks. In the case of Ocaliva, the FDA determined that a REMS was necessary, even though Intercept had not submitted a proposed REMS plan. The specific concern was for patients with moderate or severe hepatic impairment, for whom the recommended and maximum dose could be too high. For patients with moderate or severe hepatic impairment, the labeling and REMS plan require a starting dosage of 5mg orally once weekly. This starting dose may be doubled to 5mg twice weekly if the patient has not achieved an adequate reduction in ALP after 3 months and the patient is tolerating the drug; and then the dose may be further increased to 5mg every other day. Under no circumstances can a patient with moderate or severe hepatic impairment take a dosage of 10mg of Ocaliva per day or higher.

70. The risk of high dose Ocaliva and the concern for patients with hepatic impairment have been the subject of extensive discussion between Intercept and the

FDA. During a "Mid-Cycle Communication" meeting on October 27, 2015, the FDA informed Intercept that: "We are concerned that the population enrolled in the clinical trial 747-301 is not representative of the broader population of patients with PBC. The trial population represents only patients with early stage disease and therefore the results of the trial will represent efficacy and safety only in this population. The safety, efficacy and optimal dosing of Ocaliva in patients with moderately advanced or advanced stage of disease cannot be established. This may be reflected in the labeled indication."

71. This concern was reiterated at a "Late-Cycle Meeting" on March 22, 2016, when the FDA raised "Major Labeling Issues" with Intercept. During that meeting, the FDA informed Intercept that the "dose adjustment for patients with moderate and severe hepatic impairment is still under review." The FDA reviewers proposed a reduced dosing protocol similar to what was ultimately approved, with the exception that 10mg of Ocaliva would be taken twice a week.

72. Intercept concurred that "a modified dosing scheme for patients with moderate and severe hepatic impairment is warranted," but it proposed a crucial modification that could help the company maximize profits. Claiming that the purpose was "to improve compliance and optimal therapeutic response," Intercept proposed "a slight modification" of 5mg every other day instead of a 10mg twice weekly as a ceiling for patients with hepatic impairment.

73. The FDA acquiesced to the proposal and indeed, on the face of it, this approach would result in hepatically-impaired patients taking slightly less drug;

17.5mg per week rather than 20 mg per week. However, because Intercept intended to charge the same price for both the 5mg and 10mg pills, its proposal would have patients taking 4 pills per week instead of 2. This sleight of hand doubled the revenue that Intercept could make from hepatically-impaired patients.

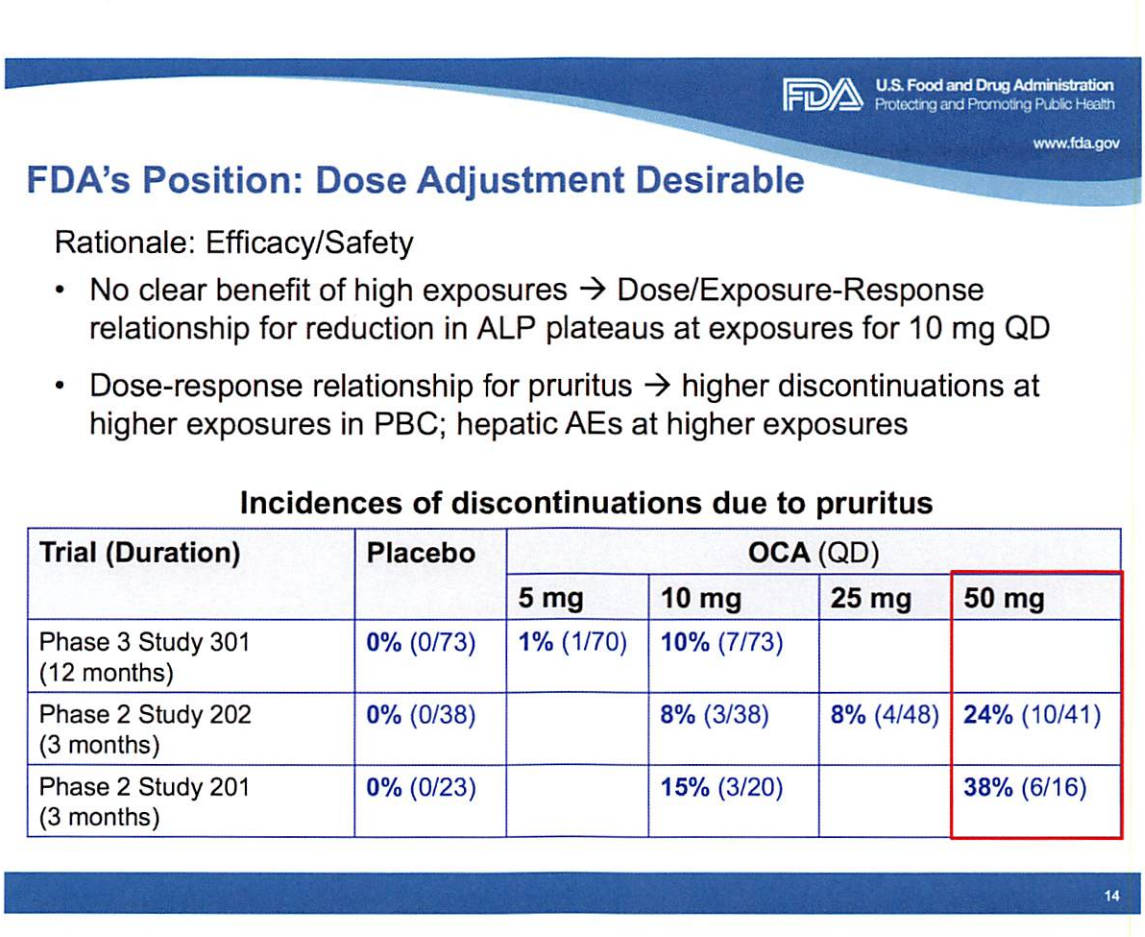
74. Pricing parity between the 5mg and 10mg doses also created a financial temptation to promote Ocaliva at higher doses. 10mg per day is the maximum dose under the FDA-approved label. Any increase above the 10mg per day maximum – whether an increase of 5mg or 10mg – would require an additional tablet every day and, again, double Intercept's revenue.

75. One month later, the FDA convened an Advisory Committee meeting. Dosing concerns were raised during this meeting as well. Although the advisory committee members generally agreed with the proposed dosing amounts, members commented that the increased incidence of hepatic adverse events at the 10mg dose "is concerning." Committee members also warned of higher doses, finding "no further increase in ALP response seen beyond 10-milligram dose in the PBC patients" and "no clear benefit of such high exposures." Indeed, according to the data, the reduction in ALP flattens out at doses of 10mg per day.

76. More importantly, committee members saw a "dose response relationship" for adverse events, with hepatic adverse events appearing to correspond to high doses. Members also commented on "discontinuations at higher exposures" to Ocaliva. In the end, a majority of the committee commented on the "insufficient data"

to support dosing of Ocaliva in PBC patients with moderately advanced (Child-Pugh B) and advanced (Child-Pugh C) cirrhosis and called for additional studies.

77. The following FDA slide summarizes the agency's dosing concerns:



U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

FDA's Position: Dose Adjustment Desirable

Rationale: Efficacy/Safety

- No clear benefit of high exposures → Dose/Exposure-Response relationship for reduction in ALP plateaus at exposures for 10 mg QD
- Dose-response relationship for pruritus → higher discontinuations at higher exposures in PBC; hepatic AEs at higher exposures

Incidences of discontinuations due to pruritus

Trial (Duration)	Placebo	OCA (QD)			
		5 mg	10 mg	25 mg	50 mg
Phase 3 Study 301 (12 months)	**0%** (0/73)	**1%** (1/70)	**10%** (7/73)		
Phase 2 Study 202 (3 months)	**0%** (0/38)		**8%** (3/38)	**8%** (4/48)	**24%** (10/41)
Phase 2 Study 201 (3 months)	**0%** (0/23)		**15%** (3/20)		**38%** (6/16)

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III. FLINT AND REGENERATE MEDICAL TRIALS

78. Intercept has conducted a Phase II trial, called the Farnesoid X Receptor (FXR) Ligand Obeticholic Acid in Nonalcoholic Steatohepatitis (NASH) Treatment (FLINT) Trial – the "FLINT" trial. The trial studied a higher dose of obeticholic acid—25mg per day, which is more than twice the maximum approved dose for treating PBC—to treat NASH for 72 weeks.

79. The FLINT trial is noteworthy because Intercept reported that it was terminated early due to meeting a pre-specified superiority endpoint during an interim analysis to avoid unnecessary biopsies. But in reality, an important reason for stopping the study early was because of a "finding of significant lipid abnormalities (increased total cholesterol, increased LDL cholesterol and decreased HDL cholesterol)." The finding was made by NIH's National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK").

80. When Intercept announced the FLINT trial results, its press release made no mention of NIH's concerns about lipid abnormalities. Indeed, the press release made no mention of any side effects or adverse events. This was no mere oversight. Patients Ocaliva experienced severe or life-threatening adverse events, and the number of patients who experienced serious adverse events was roughly 40% higher in the group treated with 25mg per day of Ocaliva than it was in the group treated with placebo. Two patients on Ocaliva died, compared with none in the placebo group.

81. Intercept's press release was so misleading that NIH was forced to correct the public record and disclose all reasons for the early termination. But even this disclosure did not alert the public to the concern about deaths of patients on higher dose Ocaliva.

82. At present, Intercept is conducting a Phase III trial for the use of Ocaliva in NASH patients. The trial is called, the Randomized Global Phase 3 Study to Evaluate the Impact on NASH With Fibrosis of Obeticholic Acid Treatment (REGENERATE, or ReGENrATe) (NCT02548351). The study is designed to compare

placebo to two treatment arms, one taking 10mg per day of Ocaliva and the other taking 25mg per day of Ocaliva. The target completion date is October 2021.

83. In February 2017, Intercept announced that after discussions with the FDA, it had changed REGENERATE's primary endpoint from fibrosis improvement ***and*** NASH resolution to fibrosis improvement ***or*** NASH resolution. Thus, instead of needing to demonstrate both endpoints, Intercept now had lowered the bar by only having to achieve one—a "best case scenario" for the company given the NASH market could be worth tens of billions of dollars.

84. The effect of the change also favorably reduced the number of patients needed for an interim analysis. Although the trial called for 2,000 patients, the interim cohort size for the NASH resolution endpoint (as used in FLINT) was 1,400 patients. But using the new definition, the requisite cohort size dropped to 750 patients. Despite slow enrollment, Intercept's CEO Mark Pruzanski, M.D. forecast that a data readout should still be ready by 2019, and that interim cohort enrollment should be achieved "mid-2017," rather than "within the first half of 2017" as previously forecast.

85. In June 2017, Intercept announced a favorable post-hoc data analysis from the FLINT study, but once against failed to mention the termination of the study due to lipid anomalies. Indeed, the only side effect mentioned was itchy skin (pruritus). No mention of severe or life-threatening adverse events was made, nor was there any mention that they were experienced disproportionately in the group treated with higher-dose Ocaliva. Nor was it referenced that two of the Ocaliva patients died during the study.

86. Just three months later, on September 8, 2017, Intercept was required to send a "Dear Doctor" letter warning about liver injury, liver decompensation, liver failure, and death in patients with moderate to severe hepatic impairment when Ocaliva was dosed more frequently than recommended in the labeling for such patients. While this news may have come as a surprise to the public, it was not a surprise to Intercept, who had know about the risk of death for years but concealed it. More bad news was to follow.

87. On September 21, 2017, the FDA announced that in the 13 months since Ocaliva (obeticholic acid) was cleared for use in May 2016 for the treatment of PBC, 19 cases of death had been identified, of which 8 provided information about the cause of death. The cause of death was reported to be worsening of PBC disease in 7 cases, with cardiovascular disease cited in the other case. Crucially, in 7 of these 8 cases, patients with moderate to severe decreased liver function were receiving Ocaliva 5mg daily, instead of a dose no greater than 10mg twice weekly as recommended by the FDA.

88. By the end of August 2017, the number of reported deaths of patients taking Ocaliva had grown to 24.

IV. THE OFF-LABEL PROMOTION OF OCALIVA FOR THE TREATMENT OF NASH

89. Notwithstanding the risks associated with off-label and high-dose use of Ocaliva, Intercept marketed the drug for the treatment of NASH, for hepatic-impaired patients, and at higher than approved doses. Relator has first-hand knowledge and experience of this marketing push into the NASH off-label market and, although it is

not uncommon for pharmaceutical companies to stray "off label," it is a particularly dangerous and harmful practice where there is no scientific support for any given off-label use or indeed any variation in FDA-approved dosing in the face of significant safety concerns, including death.

90. The approved dosing regime is 5mg Ocaliva daily, unless after three months, the patient shows insufficient reduction in alkaline phosphate levels, in which case the dose may be increased to 10mg per day. However, the REGENERATE trial currently underway involves a dosing regimen of 25mg per day, a level of dosing that recently has been shown to be very dangerous.

91. Nevertheless, Intercept has been encouraging its sales representatives to "push the dose" whether for a more effective "off-label" treatment of PBC, or for the treatment of NASH. Relator observed this behavior first hand and reported it to his manager Kevin Clarke, Sr. Director, Market Access. Clarke told Relator, "It's not your problem, forget it."

92. Relator also witnessed numerous occasions in which company staff engaged in off-label promotion. Both sales representatives, and the supposedly more independent medical science liaison ("MSL") staff, have been promoting off-label use, for example:

- MSL Marueen Cormier promoted Ocaliva at higher dosing levels in a meeting with Harvard Pilgrim Health Care, citing interim Phase 3 trial results;

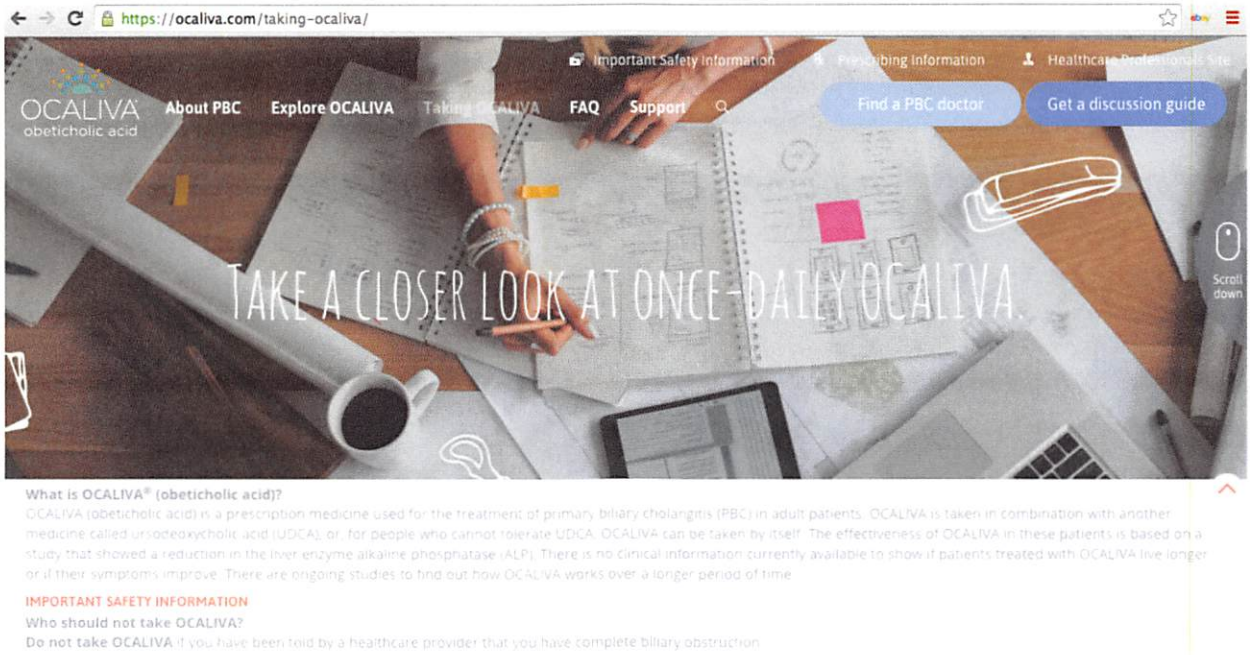
- MSL Travis Cooper used the interim Phase 3 trial results to support increased dosing levels in meetings with doctors in his Louisiana territory;
- MSL Shawn Baker discussed specific patients among the REGENERATE trial data with Dr. Bárbara Rosado Carrión of Ponce, Puerto Rico, during the course of the trial when neither Dr. Rosado Carrión nor Baker should have known the specific patient identities;
- Sales representative Ricky Corales promoted Ocaliva for the treatment of NASH to Dr. Bzowej at Ochsner Medical Center, Jefferson, Louisiana;
- Sales representative, Dar Russell, visited doctors in Puerto Rico with Relator. During those visits, Russell promoted Ocaliva as safe and effective for the treatment of NASH citing interim results of the REGENERATE trial;
- Sales representative Misty Orr promoted Ocaliva for the treatment of NASH to multiple doctors and clinical pharmacists at Vanderbilt Medical Center, Nashville Tennessee – again improperly discussing the patients in question by name.

93. Tragically, the effort to promote high doses of Ocaliva for patients with hepatic impairment has been successful. Indeed, prior to an investor conference call to respond to the recently announced connection between Ocaliva and patient deaths, Intercept issued a statement where the company revealed the following:

> In the course of Intercept's post-marketing pharmacovigilance activities, deaths have been reported in PBC patients ***with moderate or severe hepatic impairment*** (Child Pugh B or C cirrhosis). In an analysis performed by Intercept and in consultation with the FDA, Intercept concluded that ***these patients*** were prescribed ***once daily doses*** of Ocaliva, which is ***seven times higher*** than the recommended weekly dose in such patients

94. With this statement, Intercept admitted that: (a) patients with hepatic impairment were receiving daily doses of Ocaliva, when at best they should have only been taking the drug on alternating days; and (b) that the weekly dosages for patients with hepatic impairment were seven times higher than approved. Intercept has not revealed the underlying data, but the implications are clear. Either new patients with hepatic impairment were being started on 5mg per day when they should have been taking only one 5mg pill per week, or they were taking 10mg per day when they should have been taking only two 5mg pills per week, or they were taking 20 mg per day, when they should have been taking one 5mg pill every other day.

95. Intercept's marketing of Ocaliva as a daily dosage drug, regardless of hepatic impairment, is evident even on the product's website: ocaliva.com. The need to reduce the dosage and frequency for patients with hepatic impairment is not prominently mentioned. Instead, patients are invited to "take a closer look at ***once-daily*** Ocaliva":



96. And neither the main page, the page discussing "Dosing," the page discussing "Side Effects," or the page discussing "Important Safety Information" disclose the risks of high dose, the need for patients with hepatic impairment to take lower and less frequent doses, and the possibility of death. Such information is only available for patients and doctors who download the FDA-approved package insert.

V. INTERCEPT PAID PATIENT KICKBACKS TO INDUCE OCALIVA PRESCRIPTIONS

97. Intercept operates a patient assistance program through a company called TMS Health, LLC ("TMS Health"), now part of Conduent Incorporated. Conduent is a business process company headquartered in New Jersey founded earlier this year as a spin off from Xerox Corporation. The company has 93,000 employees. According to the terms of an agreement between Intercept and TMS Health, TMS Health agreed to establish a "HUB Patient Reimbursement and Patient Assistance Support Center" to eradicate reimbursement barriers and provide education to doctors' offices and,

crucially, to "provide information and support as required to the Intercept Sales Team." Under the terms of the agreement, "The RDs [regional directors] and TBMs [territory business managers] will be provided de-identified Activity and case status dashboards on a mutually agreed upon frequency."

98. TMS Health established the Intercept Patient Support Service (known as "Interconnect"), which was ostensibly an independent service aimed at educating patients and assisting them through the reimbursement process. In reality, TMS Health acted like an extension of the Intercept sales force, promoting Ocaliva and identifying potential patients for Intercept sales representatives. For example, when Interconnect case managers such as Cortney Burton and Alex D'Amato first communicated with a new doctor or doctor's office, they would ask probing questions to find out if there were other potential Ocaliva patients within the practice. Relator observed this "telemarketing" groundwork on many occasions when visiting Interconnect offices. The Interconnect case managers would then pass this information along to the sales representatives who would then follow up on the leads developed by Interconnect. Contrary to the terms of the agreement between TMS Health and Intercept, far from de-identifying patient information, TMS Health (via Interconnect) actively provided such information to Intercept.

99. Moreover, Interconnect was also paid like a sales force; the greater the number of prescriptions that Interconnect processed, the greater its pay. Relator estimates that Intercept paid Interconnect roughly $4 million in Interconnect's first year of operation.

100. According to internal Intercept documentation, beneficiaries of Government Health Care Programs were to be treated differently than those with commercial insurance. Unlike commercially insured patients who automatically received co-pay assistance, "*[a]ny patient covered by gov't (Medicare/Medicaid) will be triaged to a 501c3 Foundation.*" In theory, this meant that if a Medicare patient were to receive co-pay assistance, it would be through a charity administering donations for the alleviation of the medical condition PBC; not a shill corporation handing out money to pay specifically for Ocaliva.

101. Other internal Intercept documentation establishes that Intercept, conscious that it could not legally induce Medicare and Medicaid patients with cash incentives, sought to circumvent kickback laws by engaging another, supposedly-independent party to do its dirty work.

102. The scheme was the brainchild of Keith White, Intercept's Executive Director of Market Access. The proposal was to donate money to a charitable fund with the understanding that any donations would end up subsidizing the cost of Ocaliva, rather than subsidizing the cost of treating the disease state PBC. Relator was party to conversations between White and another Intercept executive, Dave MacLeod (Sr. Director of Patient Services and Channel Operations). White and MacLeod discussed making earmarked "donations" to a charitable fund allowing Intercept to eliminate co-payments for Medicare beneficiaries.

103. The chosen charitable intermediary was The Assistance Fund, Inc. (the "Fund"), a 501(3)(c) charity founded in 2009 by Jeffery Spafford, a graduate of Harvard

Business School, with a background in specialty pharmacies. The Fund was founded with the ostensible mission to "assist under-insured patients with chronic diseases to afford advanced biotech therapies necessary to treat the patient [*sic*] chronic diseases." In its first year, the Fund received $20 million in grants and contributions, of which it awarded approximately $11 million, leaving it with roughly $9 million in assets. In its most recent IRS Form 990, the Fund stated that it had received $92 million in grants and contributions, of which it awarded $79 million, leaving the Fund with accumulated assets of $77 million, up from $69 million the year before.

104. Relator was privy to discussions concerning Intercept's first $1 million donation to the Fund. According to White, this sum lasted just a few months, during which time the Fund had distributed all the entire $1 million to subsidize Ocaliva prescriptions. Pleased with its success, Intercept made a repeat donation, again at around $1 million, and enough to subsidize roughly 66 prescriptions at $15,000 per patient. The executives at Intercept conceived of and implemented this scheme in a attempt to circumvent anti-kickback laws. By the same token, the Fund and its officers, executives, and agents also knew that accepting and distributing "ear-marked" donations was unlawful.

105. The Fund's website (*tafcares.org*) displays three advisory opinions issued by the Office of the Inspector General ("OIG") regarding the terms upon which the Fund may distribute co-pay assistance funds.[5] The letters are dated May, 26, 2010,

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[5] Although the names of the recipients of the opinions are redacted from the three letters, the Fund itself concedes that it received such regulatory guidance from the OIG.

May 19, 2011 and May 5, 2016 (the "Advisory Opinions"). The Advisory Opinions explain that "a bona fide charitable organization" may distribute co-pay assistance funds even though they "could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal healthcare program business were present." However, if the distribution were conducted under tightly-controlled circumstances, then the Fund might distribute funds without incurring liability under the Federal kickback statute. Relator is aware that the Fund distributed the Intercept "donations" in a manner that runs afoul of the Advisory Opinions in numerous ways, including:

- Patients were eligible for co-pay assistance only if the prescription was for Ocaliva rather than simply the disease state PBC;
- The Fund falsely certified that it would not "refer applicants to, recommend, or arrange for the use of any particular medication." In fact, the Fund had agreed with Intercept to use the "donations" to fund prescriptions for Ocaliva;
- The Fund further certified that it "would not provide Donors with any individual patient information." In fact, Relator knows that this information was provided to Intercept via case managers at Interconnect such as Courtney Burton and Alice D'Amato;
- The OIG specifically cautioned that the Fund "would not provide Donors with any data that would facilitate the Donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products." Again, this was precisely the kind of information that the Fund provided to Intercept,

among other things, alerting the company when the initial million-dollar donation had been spent.

106. The very existence of the Advisory Opinions evidences scienter on the part of the Fund because, by virtue of the advice, it knew that administering Intercept donations in this manner constituted serial breaches of the Federal Anti-Kickback statute. Furthermore, the Anti-Kickback statute was amended, effective March 23, 2010, to expressly provide that: "In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Consequently, any kickbacks paid to induce Ocaliva prescriptions on or after March 23, 2010, that caused reimbursement claims to be presented to the government for payment result in actionable false claims.

VI. HIPAA VIOLATIONS

107. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 42 U.S.C. § 201, *et seq.*, established rules protecting the privacy and security of individually-identifiable health information. The HIPAA "Privacy Rule" and "Security Rule" set Federal standards for the maintenance of the confidentiality, integrity, and availability of protected health information. Failure to comply with HIPAA can result in civil and criminal penalties.

108. Under 42 U.S.C. § 1320d-6(b), the wrongful disclosure of individually-identifiable health information is a criminal offense punishable with up to a year of imprisonment (where the breach was unknowing or with reasonable cause); up to five

years of imprisonment (where the breach was made under false pretenses); and up to ten years (where the breach was for commercial gain).

109. In the course of carrying out their illicit business, Intercept, TMS Health (via the patient service team Interconnect) and the Fund unlawfully used and shared HIPAA-protected patient information for commercial gain – the most serious of the criminal offenses outlined in 42 U.S.C. § 1320d-6(b)(3). The flow of information was a two-way street: TMS Health and the Fund would provide patient information to Intercept; and, when Intercept sales representatives encountered a potential Medicare or Medicaid candidate for Ocaliva, they would steer them to the Fund and explain that the Fund would take care of the co-pay.

110. In the course of his employment, Relator was required to compile a spreadsheet of patient names, their doctors' identities, and other HIPAA-protected information. This document was compiled with input from TMS Health, the Fund, and the Intercept sales force and was known by various names; the "Tracking Report" or the "Year End Medicare Reauthorization Report." This report was circulated by email and by hand among the Intercept sales team, the case managers at Interconnect, and Relator's team (Strategic Accounts). The reports used patient identifiers, rather than actual patient names, but when the reports were discussed in meetings, real patient data (*e.g.*, patient names and doctors' names) were used.

111. In one example of this "teamwork" from March 29, 2017, Relator was in a ride-along with Intercept sales representative Frank Cortazzo when Alice D'Amato, the Interconnect case manager, called Cortazzo on his cell phone. Cortazzo took the call

over the car's sound system and the Interconnect case manager passed along several patient names and conditions to prepare the sales representative for a meeting he was going to have with the patient's doctor.

112. On another occasion in June of 2017, sales representative Lindsey Literati requested and was provided with the names of all potential patients at the Mayo Clinic in Jacksonville, Florida. This information as compiled and provided by Relator working with Alice D'Amato and Interconnect/Intercept field liaison Terrena Sanks. The team members at Interconnect who passed confidential patient information were case managers Terrena Sanks and Alice D'Amato. Relator witnessed a similar exchange between Interconnect case manager Angela Bury and Intercept sales representative Mark Robinson, in which the Interconnect nurse passed along the identity of a potential target in the last week of January 2017. Such illicit interactions were commonplace.

113. For example, in the case of A.A., a patient with PBC, Blue Cross Blue Shield of Tennessee wrote to the patient denying coverage for Ocaliva. This letter dated June 30, 2016 was addressed to A.A. and explained the basis for the denial; yet it found its way over to Intercept via the supposedly independent patient services corporation, Interconnect. Such criminal exploitation of personal medical information was an essential part of the arrangement between TMS Health's Interconnect and its partner-in-crime Intercept. In this way, staff at Intercept could manage the payment system to ensure its own reimbursement while all the time patients thought their information was protected by an organization that supposedly existed for their benefit.

114. In one example of an egregious breach of HIPAA regulations, sales representative Melissa Guerin had not only received the name of patient #5083, she had actually spoken with the patient several times. Indeed, Ms. Guerin promised that patient that they would receive company from the Patient Assistance Program ("PAP"). In an email to Relator dated March 31, 2017, Ms. Guerin demonstrates an intimate knowledge of the patient's blood work – "Patient's ALP is 440! … show[s] no signs of cholestasis?!" – information that Interconnect improperly shared with Intercept. Ms. Guerin recounts conversations with the doctor's office regarding this patient and mentions Dr. N. by name.

115. At the time of this promise in June 2017, sales representatives were under great pressure to achieve sales targets and representatives were receiving bonuses regardless of the source of the payment for the prescription. From conversations with Ms. Guerin, Relator knows that she ordered Interconnect case managers Tamika Gibson and Cortney Burton to approve PAP funds, which they did despite the fact that patient #5083 had commercial insurance. This arrangement made no financial sense for Intercept but it ensured that Ms. Guerin would receive credit for one more prescription and highlights the unhealthy power dynamic between Intercept and the supposedly independent Interconnect.

116. The ensuing email chain involved numerous people from Intercept and Interconnect and it illustrates a cavalier attitude to patient privacy – although the patient is not named in the email chain, the patient's name was used in many subsequent conversations. On May 15, 2017, Kevin Clarke (Sr. Director of Market

Access) advises the email recipients: "Let's not continue an email chain with our internal conversations." Mr. Clarke does not comment that patient data should never be shared in this fashion; rather he suggests that the parties "schedule a call" instead of putting things in writing.

117. In the same email chain Ms. Guerin inquires as to Medicare Patient #6173 and why there is a hold up with the authorization of increasing the Ocaliva dose from 5mg to 10mg. Again Ms. Guerin had spoken to the patient, the doctor's office as well as Interconnect regarding the patient's upward titration. Ultimately, the Fund paid the patient's 20% co-pay despite the fact that they had Accredo as a secondary form of insurance. The patient did not qualify for co-pay assistance; it was simply more convenient for Ms. Guerin to achieve her sales goal through the Fund rather than deal with the co-insurance for the co-pay.

118. Such illicit communications were common. Relator recalls another email exchange regarding patient #8383 in which Tamika Gibson of Interconnect emailed HIPAA-protected data to Intercept and approved patient assistance funds without following any approval procedures. Ms. Burton, her superior, ordered those emails recalled.

VII. KICKBACKS TO PRESCRIBERS

119. Relator is aware that Intercept recently has been installing Fibroscan machines in the offices of doctors who have signed up to participate in the REGENERATE Phase 3 trial. These machines allow for a non-invasive evaluation of the status of the liver in patients with liver disease and cost approximately $100,000. One of

the reasons that the enrollment for the Phase 3 trial has been slow is that there is a backlog in the processing of liver biopsies for potential participants. Thus, although there might be a legitimate need for the temporary placement of the Fibroscan machines, on information and belief, recipients have been using these machines for commercial purposes and billing for such services. Intercept is aware of the potential for recipients to profit from the use of its machines but the company is either turning a blind eye to the practice, or it is positively complicit in what may amount to a kickback arrangement.

120. Intercept also has held many practitioner Advisory Board meetings, both before and after the approval of Ocaliva, as a means to use travel and entertainment as a way to influence prescribers. Prior to launch, Intercept held advisory boards in numerous major cities, including Dallas, Denver, Atlanta, Miami, and New York; and the company paid doctors $2,500 to $3,500 to attend those meetings, and also paid for the doctors' flights and accommodation. For example, one such Advisory Board was held in Atlanta on May 6, 2017. The board was intended to influence nurse practitioners who were paid an honorarium of $1,750 to attend the half-day meeting. Intercept also paid for flights, hotels, and meals. In addition to being an inducement for writing Ocaliva prescriptions, these advisory boards served as a forum for the discussion and dissemination of information on the off-label use of Ocaliva in the treatment of NASH.

121. Furthermore, Intercept actively used speaking fees as a means to influence prescribers. Intercept paid physicians approximately $3,000 for speaking engagements.

These payments were intended to induce the speaker to write further prescriptions for Ocaliva and as such constitute unlawful payments under the Anti-Kickback Statute.

LEGAL CLAIMS FOR RELIEF

122. Relator alleges that Defendants' conduct detailed above violates the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.* (Counts I & II), and violates the analog false claims acts of the Plaintiff States and the District (Counts III-XXXI). He brings these claims on behalf of the United States, the Plaintiff States, and the District, as well as on his own behalf.

CLAIMS ON BEHALF OF THE UNITED STATES

COUNT I
Federal False Claims Act
31 U.S.C. § 3729, *et seq.*
False Claims Based on Off-Label Marketing

123. Relator repeats and realleges the allegations set forth in Paragraphs 1 through 122 as if set forth fully herein.

124. This is a claim for treble damages and penalties against Defendants under the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*

125. As described in detail above, Defendants have caused the presentation of numerous false claims to the United States through the Medicare and Medicaid programs and other federal Government Health Care Programs for reimbursement of prescriptions of Ocaliva caused by off-label marketing for unapproved uses. The unapproved uses are ones that the FDA specifically has refused to allow Defendants to

market to, and there are no citations or supporting references in any of the federally-recognized compendia that would justify the unapproved uses.

126. Through its various marketing activities and its LSM sales representatives, Defendants encourage doctors to prescribe Ocaliva for off-label uses, knowing that patients are reasonably likely to have Medicare or Medicaid coverage. Thus at all times, Defendants know and have known that their marketing would cause Medicare, Medicaid, and other Government Health Care Programs to pay for unapproved uses of Ocaliva.

127. Furthermore, in the regular course of its marketing, Defendants make false statements to physicians that cause claims to be presented to Medicare, Medicaid, and other federal Government Health Care Programs, and are material to the decisions to pay those claims. Specifically, Defendants falsely state that the definition of PBC is based on the phenotype, not the genotype; and Defendants falsely state that a patient who does not have a confirmed diagnosis of PBC based on a genetic test nevertheless has PBC based on a functional diagnosis that the FDA has rejected. Such statements are false and Defendants know they are false. They are made for the express purpose of soliciting and causing off-label prescriptions that will result in the presentation of false claims to the government.

128. Defendants' false statements were material to false or fraudulent claims. Had Defendants informed their customers that Medicare, Medicaid and the federal Government Health Care Programs would not consider the prescriptions to be within